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WRITTEN OPINION OF THE
INTERNATIONAL SEARCHING
AUTHORITY (SEPARATE SHEET)

International application Nr

PCT/FR2004/002306

Concerning point V

Reasoned statement pursuant to rule 66.2(a)(ii) with regard to novelty, inventive step and industrial application; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP 0966983

D2: FR 2835753

D3: FR 2830765

Inventive step Article 33(3) PCT

2. The present application does not satisfy the requirements of article 33(1) PCT, since the subject matter of claims 1-6 does not seem to involve any inventive step as defined by article 33(3) PCT.
- 2.1. Document D1, which is considered as the closest prior art with regard to the subject matter of claim 6, describes (references between brackets apply to this document) a device for protecting an injection apparatus including :
 - a support sleeve (26) comprising a body able to accommodate the injection apparatus (12) and a proximal end part (upper part 38),
 - a protective sleeve (28) able to slide with respect to the support sleeve (26) between a retracted standby configuration in which the needle is exposed (Fig. 3) and a deployed protective configuration in which it covers the needle (Fig. 4),
 - first retaining means (48 + 58) for holding the protective sleeve (28) in its standby configuration in a first position, known as the injection position,
 - second retaining means (54 + 58) for holding the protective sleeve (28) in its so-called end-of-injection position,

- an intermediate collar (32) situated in the proximal end part of the support sleeve (26), able to slide with respect to this support sleeve within the said proximal end part, the said collar (32) comprising means (66 + 30) of deactivating the said first and second retaining means,
- the said first retaining means (48 + 58) being able to be deactivated by the said deactivation means of the said intermediate collar by ^{RELEASE OF} pressure of the piston head in the distal direction on the said means of collaboration, so as to cause the protective sleeve to slide in its standby configuration, between the injection position and the end-of-injection position,
- pushing means (spring (30))

Consequently, the subject matter of claim 1 differs from the known device of D1 in that:

- the intermediate collar includes **collaboration means with the piston head**, and the said second retaining means are deactivated by the deactivation means by release of the pressure of the piston head on the said collaboration means, so as to allow the protective sleeve to deploy under the action of the pushing means.

The problem the present invention intends to solve can therefore be considered as being the following: how is it possible to obtain a protective device which may be activated automatically, but only at the end of injection or when the user decides to.

Document D2 describes a collar (16) whose collaboration means (activation tongues 29 and 31) are deactivated by the piston head and allow the protective sleeve to deploy at the end of injection only.

Consequently, **claims 1 and 6** do not seem to involve any inventive step (Article PCT 33(3)).

2.2. Document D2 also describes:

- collaboration means (29 and 31) including two diametrically opposite legs (Fig. 2a)

Consequently, the subject matter of **claim 2** does not seem to involve any inventive step.

2.3 **Claims 3-5** define a slight constructive amendment to the device (retaining means) described in claim 1; this amendment belongs to common practice for the person skilled in the art, and the resulting advantages are easily predictable. Consequently, the subject matter of claims 3-5 does not seem to involve any inventive step.

Other comments

3. Contrary to the requirements of rule 5.1 a) ii) PCT, the description does not state the relevant prior art set out in documents **D1-D4** and does not cite these documents.

Concerning point VI

Some cited documents

Some published documents

| Application Nr Patent Nr | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (validly claimed) (day/month/year) |
|-----------------------------|--------------------------------------|---------------------------------|---|
| US2003/0212380 | 13/11/2003 | 10/05/2002 | 10/05/2002 |

According to document D4, the technical features of claims 1, 2 and 6 do not seem novel (Figures 1-25).

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**INTERNATIONAL PRELIMINARY
REPORT ON PATENTABILITY
(SEPARATE SHEET)**

International application Nr

PCT/FR2004/002306

Concerning point V

Reasoned statement pursuant to rule 66.2(a)(ii) with regard to novelty, inventive step and industrial application; citations and explanations supporting such statement

1. Reference is made to the following documents:

D1: EP 0966983

D2: FR 2835753

Novelty Article 33(2) and Inventive step Article 33(3) PCT

2. Document D1, which is considered as the closest prior art with regard to the subject matter of claim 1, describes (references between brackets apply to this document) a device for protecting an injection apparatus including :
 - a support sleeve (26) comprising a body able to accommodate the injection apparatus (12) and a proximal end part (upper part 38),
 - a protective sleeve (28) able to slide with respect to the support sleeve (26) between a retracted standby configuration in which the needle is exposed (Fig. 3) and a deployed protective configuration in which it covers the needle (Fig. 4),
 - first retaining means (48 + 58) for holding the protective sleeve (28) in its standby configuration in a first position, known as the injection position,
 - an intermediate collar (32) situated in the proximal end part of the support sleeve (26), able to slide with respect to this support sleeve within the said proximal end part, the said collar (32) comprising means (66 + 30) of deactivating the said first and second retaining means,
 - the said first retaining means (48 + 58) being able to be deactivated by the said deactivation means of the said intermediate collar by pressure of the piston head in the distal direction on the said means of collaboration, so as to cause the protective sleeve to slide in its standby configuration, between the injection position and the end-of-injection position,

Consequently, the subject matter of claim 1 differs from the known device of D1 in that:

- second retaining means for holding the protective sleeve in its standby configuration in a second position, known as the end-of-injection position, noticeably offset in the distal direction with regard to the support sleeve
- said second retaining means being deactivated by the deactivation means, by release of the pressure of the piston head on the said collaboration means, so as to allow the protective sleeve to deploy under the action of the pushing means.

The problem the present invention intends to solve can therefore be considered as being the following: how is it possible to obtain a protective device which may be activated automatically, and not inadvertently.

Document D1 and document D2 do not disclose second retaining means retaining the protective sleeve in a retracted configuration even when the user pushes the piston up to the end of the stroke.

It is not obvious for the person skilled in the art to modify the injection device according to document D1 and to obtain a second retracted configuration of the protective sleeve.

Consequently, the present application satisfies the requirements of article 33(1) PCT, the subject matter of claim 1 and of the dependent claims 2-6 seems to satisfy the novelty requirement defined by article 33(2) PCT and also seems to involve inventive step as defined in article 33(3) PCT.

Concerning point VI

Some cited documents

Some published documents

| Application Nr Patent Nr | Publication date (day/month/year) | Filing date (day/month/year) | Priority date (validly claimed) (day/month/year) |
|-----------------------------|--------------------------------------|---------------------------------|---|
| EP 1558310 | 27/05/2004 | 06/11/2002 | 06/11/2002 |

According to document D5, the technical features of claims 1, 2 and 6 do not seem novel.

Concerning point VII

Some deficiencies in the international application

1. Contrary to the requirements of rule 5.1 a) ii) PCT, the description does not state the relevant prior art set out in documents D1-D2 and does not cite these documents.
2. Claim 1 includes two parts. However, the features of the first retaining means, the intermediate collar and the said first retaining means being able to be deactivated by the said deactivation means of the said intermediate collar by pressure of the piston head in the distal direction on the said means of collaboration, so as to cause the protective sleeve to slide in its standby configuration, between the injection position and the end-of-injection position, should not appear in the characterizing part, since they are disclosed in document D1, in combination with the features of the preamble (rule 6.3 b) PCT).

Concerning point VIII

Some remarks relating to the international application

Clarity Article 6 PCT

The subject matter of the claim is not clearly defined (article 6 PCT).

The phrase "in its standby configuration" used in claim 1 to define the first and second retaining means is vague and ambiguous. Information on the standby configuration (exposed needle or retracted support sleeve) would clarify the claim.